WHO Health Technology Access Program (HTAP) – A targeted approach to bridging the access gap

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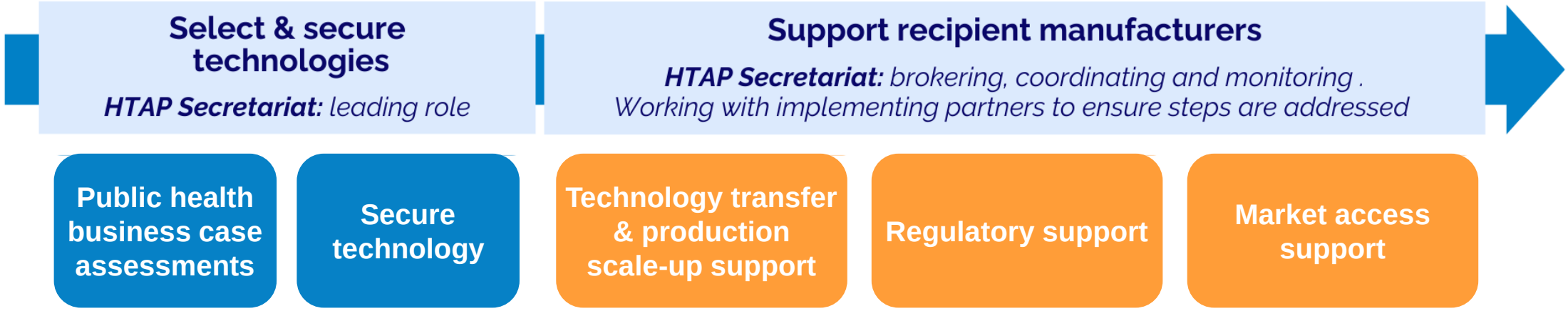
HTAP: an evolution and integration of two programs

- WHO launched C-TAP (COVID-19 Technology Access Pool) and the mRNA technology transfer programme to address access inequities seen during the pandemic
- Both programs have since evolved and now represent complementary operating models of the **WHO Health Technology Access Program :**
  - *Selecting, securing and transfer the rights and know-how to existing technologies* and supporting their geo-diversified transfer to manufacturers - *and in the longer term….*
  - *Building product development capacity* through health technology consortia
- HTAP contributes to both pandemic preparedness and response and existing public health priorities by *actively targeting platform technologies*
- Approach amplifies the attractiveness of licensed technologies to recipient manufacturers in realizing greater market opportunities and financial sustainability

HTAP – mechanism for aligning resources required to address a health technology access gap



- Using technology platforms to build capabilities in underserved regions
- Technologies selected based on the prioritization process and business case assessment
- Considers critical factors and support required to translate licenses into sustainable, diversified production -> *working in partnership with WHO programs and external partners*

SD Biosensor license: serving as a live test case

- **License**
  - SD Biosensor (SDB) - Medicines Patent Pool (MPP) license signed December 2023
  - Provides rights, know-how and material required to produce rapid diagnostic tests (RDT) based on the licensed technology
  - Territory: Worldwide, except the countries where SDB production plants are located
  - Call for Applications to receive sublicense: February 28 – May 31 2024
- **Why this is important:**
  - Multi-pathogen platform; targets include COVID-19, HIV, Malaria, Syphilis and Hepatitis
  - Sublicensed manufacturers benefit from comprehensive, phased tech transfer plan
  - Support that can be provided to address gaps in ability to absorb and sustainably produce transferred technology
- **Status: 5 applications received; 3 applicants under final review** – joint WHO-MPP effort

Reflections to date

- Goal of sublicensing: contribute to sustainable manufacture of quality-assured RDTs at competitive prices
- However, prerequistes to success are many – and complex
  - Tech transfer experience/support, realistic business strategies, access to funding, manufacturing/control/regulatory experience, regulatory maturity, supply infrastructure, procurement/demand considerations, market access, etc.
- Many companies transitioning from health product distribution to manufacturing
- HTAP selection process is designed to identify manufacturers that could successfully absorb and produce SDB technology, if adequately supported
- Requires a coordinated approach to support, drawing on strengths and mandates of relevant programs if success is to be realized

WHO programs and partners, working together under a unified support plan, could optimize support and impact

- Workforce training through WHO Biomanufacturing Training Hub/Regional Centres
- Supporting development of “investment-worthy” business plans to secure financing
- Engagement with governments, regional health agencies and procurers to develop the appropriate conditions for sustainable regional production.
- Assisting technology transfer process and production scale-up to ensure quality-assured products at competitive prices
- Strengthening regulatory systems to build trust in products
- Specialised technical assistance to reach prequalification status
- Facilitating national registrations through the Collaborative Registration Procedure

HTAP thanks donors for their support

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THANK YOU

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HTAP presentation at the NTD Dx manufacturer's workshop by Cheleka Mpande

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